K023457P1

Attachment 1: 510(k) Summary: NOV 1 2002

This summary is provided as part of this Premarket Notification in compliance with 21CRF, Section 807.92.

Submitters name: B-K Medical A/S
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Contact person: Villy Braender, Quality Assurance Mnager
Date prepared: 30.September, 2002

Trade name: Ultrasound Scanner Type 1101
Common name: Diagnostic Ultrasound System
Classification names:
Ultrasonic Pulsed Echo Imaging System (90 IYO, CFR 892.1560)
Diagnostic Ultrasonic Transducer (90 ITX, CFR 892.1570)

Identification of predicate, legally marketed device:
Siemens Medical Systems: Sonoline Elegra Diagnostic Ultrasound System (K980557)

Device description:

1101 supports the following scanning modes and combinations thereof:
B-mode M-mode.
The system can perform simple geometric measurements, and perform calculations in the areas of Urology, Cardiology and OB/GYN applications.
The system can guide biopsy- and puncture needles.

Transducers
Transducers are linear and convex arrays and mechanical sector.
The patient contact materials comply with ISO10993-1
All transducers used together with 1101 are Track 3 transducers.

Acoustic output
The system will assure that the acoustic output always will stay below the pre-amendments upper limits i.e. Ispta ≤ 720 mW/cm² and MI ≤ 1.9 (Track 3, non ophthalmic).
The Thermal Index values are maximum 6.0, i.e. TI ≤ 6.0

Clinical measurement accuracy.
Clinical measurements and calculations are described and accuracies are provided in the User Guide.

Thermal, mechanical and electrical safety.
The scanner 1101 has been tested by a recognized, certified body according to IEC 60601-1 .

Acoustic Output Reporting
The Acoustic Output Reporting is made according to the standards required by "Information for Manufacturers Seeking Clearance of Diagnostic Ultrasound Systems and Transducers, FDA, CDRH, September 30, 1997"
The acoustic output is measured and calculated according to: "Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment" (AIUM 1998).

Intended use.
See comparison below

Technological characteristics compared to the predicate device.
The predicate device has the same major technological characteristics as the subject device, see comparison below.

Comparison with K980557, Sonoline Elegra (Siemens Medical Systems).

	Type 1101 in this application	K980557, Sonoline Elegra
Intended uses	Abdominal, Cardiac, Fetal, Intraoperative, Neurosurgery, Pediatrics, Transrectal, Small organs, Transvaginal, Musculoskeletal (superficial, conventional)	General Radiology, Abdominal,Intraoperative,Small parts, transcranial,OB/GYN, Neonatal/Adult Cephalic, Urology, Vascular, Musculoskeletal, Superficial Musculoskeletal, Peripheral Vascular
General device description	B,M and combination modes, Track 3 (Index display). Measurements	B,M Color, PW, CW and combination modes. Track 3 (Index display). Measurements.
Acoustic output	Ispta $\leq$ 720 mW/cm^2 and MI $\leq$ 1.9 (Track 3, non ophthalmic). TI $\leq$ 6.0	Not in 510(k)summary, except that it has index display according to Display standard.
General safety and effectiveness	UL2601, CSA22.2 No 601-1, EN60601, 93/42/EEC Medical Devices Directive, AIUM/NEMA Display standard, EN/ISO 10993-1	UL2601, CSA22.2 No 601-1, EN60601,93/42/EEC Medical Devices Directive, AIUM/NEMA Display standard
Labeling	Please refer to section 4.8	Not in 510(k) summary)

Conclusion: The device 1101 in this application has similar intended uses, and in particular the subject for the application , musculo-skeletal, is the same.

B-K Medical A/S therefore believes, that 1101 is substantially equivalent to K980557.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 2002

Mr. Villy Brænder
Official Correspondant
B-K Medical A/S
Mileparken 34
DK-2730 Herlev
DENMARK

Re: K023457
Trade Name: Ultrasound Scanner Type 1101
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: 90 IYO and ITX
Dated: October 7, 2002
Received: October 15, 2002

Dear Mr. Brænder:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Ultrasound Scanner Type 1101, as described in your premarket notification:

Transducer Model Number
8560
8570

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

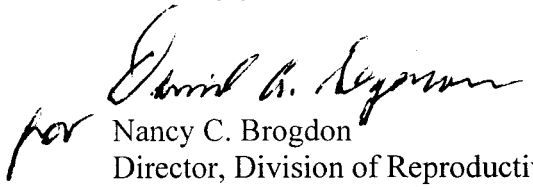
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801, please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,



for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Diagnostic Ultrasound Indications for Use Form

System: 1101

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		X	X						X (B+M)	
Abdominal		X	X						X (B+M)	
Intraoperative (specify)		X	X						X (B+M)	
Intraoperative Neurological		X	X						X (B+M)	
Pediatric		X	X						X (B+M)	
Small Organ (specify)		X	X						X (B+M)	
Neonatal Cephalic										
Adult Cephalic										
Cardiac		X	X						X (B+M)	
Transesophageal										
Transrectal		X	X						X (B+M)	
Transvaginal		X	X						X (B+M)	
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional		x	x						X (B+M)	
Musculo-skeletal Superficial		x	x						X (B+M)	
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: _____

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Hoyman

(Division Sign-Off)

Division of **Reproductive, Abdominal,** **Radiological Devices**

510(k) Number K023451

Prescription Use (Per 21 CFR 801.109)

4.3

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: 1101
Transducer: 8560

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)	P	P				P (B+M)	
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P	P				P (B+M)	
	Small Organ (Specify)	P	P				P (B+M)	
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)	N	N				N (B+M)	
	Musculo-skel. (Superficial)	N	N				N (B+M)	
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E
*Examples may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging

Additional Comments: Intraoperative: Breast, liver, pancreas, biliary system
Small Organ: Breast, testis, penis, thyroid, parathyroid, salivary glands, lymph nodes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K023457

Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: 1101
Transducer: 8570

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	E	E				E (B+M)	
	Small Organ (Specify)	E	E				E (B+M)	
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)	N	N				N (B+M)	
	Musculo-skel. (Superficial)	N	N				N (B+M)	
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added (to K002085) under Appendix E
*Examples may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging

Additional Comments: Intraoperative: Breast, liver, pancreas, biliary system
Small Organ: Breast, testis, penis, thyroid, parathyroid, salivary glands, lymph nodes

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

David A. Ferguson
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K023457

Prescription Use (Per 21 CFR 801.109)